

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference IB/G-33578A/LEK	FOR FURTHER ACTION <small>see Form PCT/ISA/220 as well as, where applicable, item 5 below.</small>	
International application No. PCT/SI2004/000047	International filing date (day/month/year) 27/12/2004	(Earliest) Priority Date (day/month/year) 29/12/2003
Applicant LEK PHARMACEUTICALS D.D.		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 7 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the language, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ The international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, see Box No. I.

2. ☐ Certain claims were found unsearchable (See Box II).

3. ☒ Unity of invention is lacking (see Box III).

4. With regard to the title,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the abstract,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the drawings,

a. the figure of the drawings to be published with the abstract is Figure No. _____

☐ as suggested by the applicant.

☐ as selected by this Authority, because the applicant failed to suggest a figure.

☐ as selected by this Authority, because this figure better characterizes the invention.

b. ☐ none of the figures is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

International Application No

PCT/SI2004/000047

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 C07C303/40 C07C303/44 C07C311/37 A61K31/18

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 C07C

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, PAJ, WPI Data, BEILSTEIN Data, CHEM ABS Data, EMBASE, BIOSIS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	✓ WO 03/035608 A (LECIVA, A.S; HAJICEK, JOSEF; SLAVIKOVA, MARKETA) 1 May 2003 (2003-05-01) cited in the application page 1, lines 4-6; examples 1-8 page 5, lines 1-7; examples 1,3,4,6-8 examples 1-8	1-4, 11-14
X Y		5,6 7
X	AT 397 960 B (YAMANOUCHI PHARMACEUTICAL CO., LTD) 25 August 1994 (1994-08-25) cited in the application page 4, lines 21-25; examples 1-4 examples 1,2 page 5, lines 42-51	1-4, 11-14
X Y		8 7
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☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

G document member of the same patent family

Date of the actual completion of the international search

1 June 2005

Date of mailing of the international search report

10/06/2005

Name and mailing address of the ISA

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INTERNATIONAL SEARCH REPORT

International Application No
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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 034 432 A (YAMANOUCHI PHARMACEUTICAL CO. LTD) 26 August 1981 (1981-08-26) cited in the application page 4, lines 9-15; example 20	1-4, 11-14
X	page 26, lines 6,7,18,19; example 20	8-10
X	WO 03/037850 A (SYNTHON B.V; HOORN, HANS, JAN; PETERS, THEODORUS, HENDRICUS, ANTONIUS;) 8 May 2003 (2003-05-08) page 1, lines 5-8; example 7	1-4, 11-14
X	page 21, lines 1,2	8-10
		7-10 /

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SI2004/000047

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☒ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

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IAP11 Rec'd PCT/PTO 26 JUN 2006

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FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 5-7, 1-4(part), 11-14(part)

Process for the preparation of tamsulosin hydrochloride by reacting R-5-(2-aminopropyl)-2-methoxybenzenesulphonamide with an excess of 1-(2-bromoethoxy)-2-ethoxybenzene in an organic solvent (Claims 5-7);
Tamsulosin hydrochloride in varying degrees of purity (Claims 1-4);
Pharmaceutical composition comprising tamsulosin hydrochloride (Claims 11-12);
Use of tamsulosin hydrochloride for the preparation of a medicament for the treatment of benign prostatic hyperplasia (Claims 13-14)

2. claims: 8-10, 1-4(part), 11-14(part)

Process for the purification of tamsulosin hydrochloride comprising recrystallising tamsulosin hydrochloride from a solution in methanol or ethanol or a mixture of ethanol and methanol (Claims 8-10);
Tamsulosin hydrochloride in varying degrees of purity (Claims 1-4);
Pharmaceutical composition comprising tamsulosin hydrochloride (Claims 11-12);
Use of tamsulosin hydrochloride for the preparation of a medicament for the treatment of benign prostatic hyperplasia (Claims 13-14)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/SI2004/000047

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 03035608	A	01-05-2003	CZ 20013848 A3 WO 03035608 A1	14-05-2003 01-05-2003
AT 397960	B	25-08-1994	JP 1037391 B JP 1553822 C JP 62114952 A AT 203286 A CA 1282077 C ES 2000382 A6 KR 9407746 B1	07-08-1989 04-04-1990 26-05-1987 15-12-1993 26-03-1991 16-02-1988 24-08-1994
EP 0034432	A	26-08-1981	JP 1443699 C JP 56110665 A JP 62052742 B AR 227533 A1 AR 230433 A1 AT 7223 T AU 541720 B2 AU 6689681 A CA 1177849 A1 DE 3163257 D1 DE 19675042 I2 EP 0034432 A2 ES 8201966 A1 GR 73827 A1 IE 50862 B1 LU 90000 A9 MX 6859 E MX 9203592 A1 NL 950014 I1 PT 72460 A , B SU 1082320 A3 SU 1181540 A3 SU 1248533 A3 US 5391825 A US 4373106 A US 4868216 A US 5447958 A US 4987152 A US 4558156 A US 4703063 A US 4731478 A US 4761500 A	08-06-1988 01-09-1981 06-11-1987 15-11-1982 30-04-1984 15-05-1984 17-01-1985 13-08-1981 13-11-1984 30-05-1984 13-06-2001 26-08-1981 01-04-1982 04-05-1984 06-08-1986 04-03-1997 08-09-1986 31-07-1992 02-12-1996 01-03-1981 23-03-1984 23-09-1985 30-07-1986 21-02-1995 08-02-1983 19-09-1989 05-09-1995 22-01-1991 10-12-1985 27-10-1987 15-03-1988 02-08-1988
WO 03037850	A	08-05-2003	US 2003109752 A1 AT 6687 U1 AT 7563 U1 AT 7487 U1 AT 7562 U1 CA 2464648 A1 CA 2464917 A1 CZ 13392 U1 CZ 13580 U1 DE 20216779 U1 DE 20216835 U1 DK 200200338 U1 DK 200200339 U1 EP 1444198 A1	12-06-2003 25-02-2004 25-05-2005 25-04-2005 25-05-2005 08-05-2003 08-05-2003 13-08-2003 15-10-2003 04-09-2003 25-09-2003 31-01-2003 31-01-2003 11-08-2004

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/SI2004/000047

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 03037850 A		EP 1444199 A1	11-08-2004
		FI 5957 U1	30-09-2003
		FI 5816 U1	06-06-2003
		FR 2832146 A1	16-05-2003
		FR 2832147 A1	16-05-2003
		WO 03037850 A1	08-05-2003
		WO 03037851 A1	08-05-2003
		NL 1021671 C2	15-05-2003
		NL 1021678 C2	15-05-2003
		US 2005096394 A1	05-05-2005